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APPLICATION NO.	FILING DATE	NAME OF FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/441,189	11/22/89	MORRISON	S 24302STAN621

EXAMINER

NISBET, T

ART UNIT	PAPER NUMBER
185	10

DATE MAILED: 09/25/90

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THE HONORABLE ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 11/22/89 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire THREE month(s), _____ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 14-38 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 14-38 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 14-38 are rejected under 35 U.S.C. 112, first paragraph, as enabling only for the claims limited to DNA constructs for expression of a chimeric polypeptide which is a subunit of an immunoglobulin molecule. See MPEP 706.03(n) and 706.03 (z). This rejection is maintained for essentially the same reasons set forth in the previous office action.

The previous examiner held and the present examiner maintains that the instant application is not enabled for and multi-unit receptor (eg. T-cell receptors and Major Histocompatibility Complex antigens). There are essentially three reasons. These multi-chain receptors are not disclosed to contain constant and variable regions nor are methods disclosed on how to isolate the DNA in question. Second, not all cell receptors have constant and variable regions (eg. CD2, CD7, CD20, and Fc). Finally, it would require undo experimentation to isolate variable and constant region genomic sequences of these receptors for use ion cross-species chimeric constructions.

Claims 14, 28, 33, and 36 are rejected under 35 U.S.C. 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 28, 33, and 36 are indefinite by claiming constructs for a multi-unit receptor cells, and a method for expressing a multi unit receptor, but all multi-unit receptors are taught in the instant invention. Is [illegible] intended rather than the genus multi-unit receptor? If DNA

constructs encoding the supergene family of immunoglobulins, T-cell receptors and MHC antigens was intended, it should be named as such . The instant specification does not enable isolation of the DNA for both the constant and variable region genes encoding T-cell receptors or MHC antigens.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> "A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent."

Claims 14-34, and 36 are rejected under 35 U.S.C. § 102 (b) or 102 (e) as being clearly anticipated by Cabilly (L) or Cabilly (R) or Cabilly (2A).

This rejection is on the same grounds as those of the previous action. All of the above references teach DNA constructs of various chimeric immunoglobulins, subunits or fragments thereof. They also teach expression vectors for these constructs for expression in either eukaryotic or prokaryotic hosts. Cabilly even teaches the expression of the constructs in mammalian cells. In fact, the references anticipate every aspect of the instant application except the specific use of myeloma cells.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between

the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 35, and 37-38 are rejected under 35 U.S.C. 103 as being unpatentable over Cabilly (L) or Cabilly (R) or Cabilly (2A) in view of Gillies (S).

Gillies essentially solves the omission of the Cabilly references discussed supra by teaching the expression of immunoglobin genes in myeloma cells. The application of the Cabilly teaching in view of the Gillies would be obvious to one of ordinary skill in the art, especially given the fact that two of the authors of the Gillies reference are inventors of the instant application. Again, this rejection is essentially a repetition of the rejection of paper 7.

Claims 28-35 are rejected under 35 U.S.C. 103 as being unpatentable over Boss (2B) in view of Gillies (S).

Boss teaches the method of producing antibodies comprising transforming a host cell with DNA sequence encoding each of heavy and light chain of an immunoglobulin. Gillies is applied as above in teaching the use of myeloma cells for expressing heterologous products and the particular advantages of myeloma cells in expressing immunoglobulin genes. For further discussion of the rejection, applicant is referred to the previous action.

This is a file wrapper continuation of applicant's earlier application S.N. 07/090,669. All claims are drawn to the same invention claimed in the

earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

An inquiry concerning this communication should be directed to Examiner Nisbet at telephone number 703-557-5137.

RICHARD A. SCHWARTZ
PRIMARY EXAMINER
ART UNIT 185